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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,838	04/20/2004	Stephanie M. Kladakis	022956-0261	5281
21125 7590 04/11/2011 NUTTER MCCLENNEN & FISH LLP SEAPORT WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER				
WOODWARD, CHERIE MICHELLE				
ART UNIT		PAPER NUMBER		
1647				
NOTIFICATION DATE		DELIVERY MODE		
04/11/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/828,838

Applicant(s)

KLADAKIS ET AL.

Examiner

CHERIE M. WOODWARD

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-14, 16-21, 23-27, 32, 33 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-14, 16-21, 23-27, 32, 33 and 35-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/7/2010, 3/10/2011, 4/1/2011.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Formal Matters

1. Applicant's response filed 1/21/2011 is acknowledged and entered. Claims 9, 15, 22, 28-31, and 34 have been cancelled by Applicant. New claims 35-40 have been added. Claims 1-8, 10-14, 16-21, 23-27, 32, 33, and 35-40 are pending and under examination.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 12/7/2010, 3/10/2011, and 4/1/2011 have been considered. Foreign language documents have been considered only insofar as their abstracts are in English. Signed copies are attached.

Claim Rejections - 35 USC § 112, Second Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8, 10-14, 16-18, and 32 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record and the reasons set forth herein.

Applicant argues that the claims are not amenable to two or more plausible constructions. Applicant's argument is not persuasive.

The phrase "greater than" implies a definitive lower limit. The phrase "about" implies a relative range, which allows for greater or lesser limits. See, *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped.). In the case of the phrase "greater than about," the range is indefinite because no lower limit is adequately defined. The examiner suggested that the phrase "greater than" (which connotes a definitive lower limit) or "about" (which connotes a broader range above or below a recited limit) be used in the alternative. It is noted that this suggestion was followed in new claims 35-40, but the new claims do not change the interpretation or indefiniteness of the rejected claims herein. Accordingly, *Ex parte Miyazaki* (BPAI 11/19/2008) is applicable.

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-8, 10-14, 16-21, 23-27, 32, and 33 remain rejected and new claims 35-40 are rejected under 35 U.S.C. 103(a) as being obvious over Hays, US Patent 6,165,217 (26 December 2000), Hucklet et al., WO 01/85226 (published 15 November 2001) (previously cited of record), Bowman et al. (U.S. Patent Application Publication US 20020127265, 12 September 2002) (previously cited of record), and Brekke, US Patent 6,005,161 (21 December 1999), for the reasons of record and the reasons set forth herein.

Applicant argues each of the references individually. Applicant does not address the references in combination as applied in the rejection. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections

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are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As stated of record, “[i]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960). As stated of record, tensile strength and Young’s Modulus are properties are a function of the scaffold itself and are testable parameters. All of the references teach testing of these parameters as being routine. A person of ordinary skill in the art at the time of the instant invention would have reasonably known that nonwoven scaffolds with the instantly claimed density were known in the prior art. Hayes plainly teaches how to make and use nonwoven scaffolds with the requisite densities. Hayes also teaches how to test the scaffolds for the requisite physical properties and that these tests are routine in the art. A person of ordinary skill in the art at the time of the instant invention would have reasonably known that the nonwoven scaffolds of the claimed density could be matched with various with other structurally supporting material including foams, collagen, and other materials taught by Hayes, Huckle, and Bowman and that these other materials could be routinely optimized to provide the needed strength for the particular application for which they were used, as taught by Hayes and specifically for mensical repair, as taught by Huckle and Bowman. A person of ordinary skill in the art would have reasonably known that when used as a load bearing or support device, the scaffold should be able to withstand the rigors of physical activity during the initial healing phase and throughout remodeling. Further, with regard to biodegradable tissue repair scaffolds, the modulus of elasticity and suture pull-out strength (tensile strength) parameters will vary in any biodegradable polymeric composition as a factor of time and depending on the concentration of the polymer comprising the composition. See, for example, instant Figures 6A and 6B, show significantly different maximum load (suture pull-out/tensile strength) and different stiffness (modulus of elasticity) over a period of 2 weeks.

Applicant has provided no data or evidence showing that the products of the cited prior art do not have the innate physical parameters of the instant claims. In the absence of evidence to the contrary, the combinatorial references teach the instantly claimed invention.

Obviousness Type Double Patenting Rejections

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**** It is noted that Applicant responds to all of the double patenting rejections together in one statement and does not separately address them.**

10. Claims 1-8, 10-14, 16-21, 23-27, 32, and 33 remain rejected and new claims 35-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8, and 10 of U.S. Patent No. 6,884,428 (26 April 2005, benefit to 16 December 2002) in view of Hays, US Patent 6,165,217 (26 December 2000), Huckle et al., WO 01/85226 (published 15 November 2001) (previously cited of record), and Bowman et al. (U.S. Patent Application Publication US 20020127265, 12 September 2002) (previously cited of record), and Brekke, US Patent 6,005,161 (21 December 1999), for the reasons of record and the reasons set forth herein.

Applicant argues that the combination of the cited prior art references are not tenable for the reasons argued in response to the rejection under 35 USC 103(a). Applicant notes that a terminal disclaimer will be filed if warranted.

Applicant's arguments are noted. However, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As stated of record and above, "[i]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960). A person of ordinary skill in the art at the time of the instant invention would have reasonably known that nonwoven scaffolds with the instantly claimed density were known in the prior art. Hayes plainly teaches how to make and use nonwoven scaffolds with the requisite densities. Hayes also teaches how to test the scaffolds for the requisite physical properties and that these tests are routine in the art. A person of ordinary skill in the art at the time of the instant invention would have reasonably known that the nonwoven scaffolds of the claimed density could be matched with various with other structurally supporting material including foams, collagen, and other materials taught by Hayes, Huckle, and Bowman and that these other materials could be routinely optimized to provide the needed strength for the particular application for which they were used, as taught by Hayes and specifically for mensical repair, as taught by Huckle and Bowman. A person of ordinary skill in the art would have reasonably known that when used as a load bearing or support device, the scaffold should be able to withstand the rigors of physical activity during the initial healing phase and throughout remodeling. Further, with regard to biodegradable tissue repair scaffolds, the modulus of elasticity and suture pull-out strength (tensile strength) parameters will vary in any biodegradable polymeric composition as a factor of time and depending on the concentration of the polymer comprising the composition. Moreover, Applicant has provided no data or evidence showing that the products of the cited prior art do not have the innate physical parameters of the instant claims or that the cited patent would not be obvious over the instant claims.

11. Claims 1-8, 10-14, 16-21, 23-27, 32, and 33 remain rejected and new claims 35-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and

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8 of U.S. Patent No. 6,852,330 (8 February 2005, benefit to 21 December 2000) in view of Hays, US Patent 6,165,217 (26 December 2000), Huckle et al., WO 01/85226 (published 15 November 2001) (previously cited of record), Bowman et al. (U.S. Patent Application Publication US 20020127265, 12 September 2002) (previously cited of record), and Brekke, US Patent 6,005,161 (21 December 1999), for the reasons of record and the reasons set forth herein.

To avoid duplication, Applicant's response and the examiner's reply is set forth above.

12. Claims 1-8, 10-14, 16-21, 23-27, 32, and 33 remain rejected and new claims 35-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 7-9, and 13-16 of U.S. Patent No. 6,599,323 (29 July 2003) in view of Hays, US Patent 6,165,217 (26 December 2000), Huckle et al., WO 01/85226 (published 15 November 2001) (previously cited of record), Bowman et al. (U.S. Patent Application Publication US 20020127265, 12 September 2002) (previously cited of record) and Brekke, US Patent 6,005,161 (21 December 1999), for the reasons of record and the reasons set forth herein.

To avoid duplication, Applicant's response and the examiner's reply is set forth above.

13. Claims 1-8, 10-14, 16-21, 23-27, 32, and 33 remain provisionally rejected and new claims 35-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8-11 of copending Application No. 11/856,743, in view of Hays, US Patent 6,165,217 (26 December 2000), Huckle et al., WO 01/85226 (published 15 November 2001) (previously cited of record), Bowman et al. (U.S. Patent Application Publication US 20020127265, 12 September 2002) (previously cited of record), and Brekke, US Patent 6,005,161 (21 December 1999), for the reasons of record and the reasons set forth herein.

To avoid duplication, Applicant's response and the examiner's reply is set forth above.

14. Claims 1-8, 10-14, 16-21, 23-27, 32, and 33 remain provisionally rejected and new claims 35-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 7-9, 12, and 13 of copending Application No. 11/856,741, in view of Hays, US Patent 6,165,217 (26 December 2000), Huckle et al., WO 01/85226 (published 15 November 2001) (previously cited of record), Bowman et al. (U.S. Patent Application Publication US 20020127265, 12 September 2002) (previously cited of record), and Brekke, US Patent 6,005,161 (21 December 1999), for the reasons of record and the reasons set forth herein.

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To avoid duplication, Applicant's response and the examiner's reply is set forth above.

15. Claims 1-8, 10-14, 16-21, 23-27, 32, and 33 remain provisionally rejected and new claims 35-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-6, 13-18, 20-21, 42-47 of copending Application No. 10/775,034, in view of Hays, US Patent 6,165,217 (26 December 2000), Huckle et al., WO 01/85226 (published 15 November 2001) (previously cited of record), Bowman et al. (U.S. Patent Application Publication US 20020127265, 12 September 2002) (previously cited of record), and Brekke, US Patent 6,005,161 (21 December 1999), for the reasons of record and the reasons set forth herein.

To avoid duplication, Applicant's response and the examiner's reply is set forth above.

16. Claim 1-8, 10-14, 16-21, 23-27, 32, and 33 remain provisionally rejected and new claims 35-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 6-15, 30-37 of copending Application No. 10/828,841 in view of Hays, US Patent 6,165,217 (26 December 2000), Huckle et al., WO 01/85226 (published 15 November 2001) (previously cited of record), Bowman et al. (U.S. Patent Application Publication US 20020127265, 12 September 2002) (previously cited of record) and Brekke, US Patent 6,005,161 (21 December 1999), for the reasons of record and the reasons set forth herein.

To avoid duplication, Applicant's response and the examiner's reply is set forth above.

17. Claims 1-8, 10-14, 16-21, 23-27, 32, and 33 remain provisionally rejected and new claims 35-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 9, 10, 12, 14-19, and 28 of copending Application No. 10/729,046 (allowed 10/7/2010), in view of Hays, US Patent 6,165,217 (26 December 2000), Huckle et al., WO 01/85226 (published 15 November 2001) (previously cited of record), Bowman et al. (U.S. Patent Application Publication US 20020127265, 12 September 2002) (previously cited of record), and Brekke, US Patent 6,005,161 (21 December 1999), for the reasons of record and the reasons set forth herein.

To avoid duplication, Applicant's response and the examiner's reply is set forth above.

18. Claims 1-8, 10-14, 16-21, 23-27, 32, and 33 remain provisionally rejected and new claims 35-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 98-119 of copending Application No. 10/374,772, in view of Hays, US Patent 6,165,217 (26

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December 2000), Huckle et al., WO 01/85226 (published 15 November 2001) (previously cited of record), Bowman et al. (U.S. Patent Application Publication US 20020127265, 12 September 2002) (previously cited of record), and Brekke, US Patent 6,005,161 (21 December 1999), as well as Vyakarnam et al (US Patent 6,534,084), Albrecht et al., (Arch. Orthop. Trauma Surg. 1983:213-217), Naughton et al., (US Patent 5,842,477), and Chvapil (US Patent 5,078,744), for the reasons of record and the reasons set forth herein

To avoid duplication, Applicant's response and the examiner's reply is set forth above. Applicant did not respond to the citations of Vyakarnam, Albrecht, Naughton, or Chvapil.

Conclusion

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **CHERIE M. WOODWARD** whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 10:30am-7:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHERIE M WOODWARD/
Primary Examiner, Art Unit 1647